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DOCUMENT-IDENTIFIER: US 6013099 A
TITLE: Medical device for delivering a water-insoluble therapeutic salt or substance

Brief Summary Text (17):
The invention provides methods for manufacturing medical devices. Specifically, the invention provides a method for coating a medical device with a porous polymer (film or coating). The method includes: placing the medical device in a mold; placing a solution of a polymer in the mold with the medical device; wherein the solution of the polymer includes a solvent capable of phase separating from the polymer at a temperature below the freezing point of the solvent; cooling the solution of the polymer in the mold to a temperature below the freezing point of the solvent until a first fraction of particulate material is formed by solidification and phase separation of the solvent from the polymer and is dispersed within solidified polymer; cooling the solution further and at a faster rate than in the first cooling step to form a second fraction of particulate material dispersed within the solidified polymer, wherein the second fraction of particulate material has a smaller particle size than the first fraction; and removing the particulate material from the polymer to form pores therein. Preferably, the medical device is a stent and the solution includes a polyurethane dissolved in dioxane.

Detailed Description Text (3):
Referring now to FIG. 1, the stent 20 comprises a stent framework 22 and a porous material coating 24. The stent framework 22 is deformable and can be formed from a polymeric material, a metal or a combination thereof. A balloon 15 is positioned in FIG. 1 adjacent the lumen-exposed surface of the stent to facilitate delivery of the stent. The stent 20 can be modified to increase or to decrease the number of wires provided per centimeter in the stent framework 22. Similarly, the number of wire turns per centimeter can also be modified to produce a stiffer or a more flexible stent framework.

Detailed Description Text (5):
Nonbioabsorbable polymers can be used as alternatives to metallic stents. The stents of this invention should not substantially induce inflammatory and neointimal responses. Examples of biostable nonabsorbable polymers that have been used for stent construction with or without metallic elements include polyethylene terephthalate (PET), polyurethane urea and silicone (for example, see van Beusekom et al., Circulation, 86(supp. I):I-731, 1992 and Lincoff et al., J. Am. Coll Cardiol., 21(supp. 1):335A, 1994. Although the porous material is shown as a coating 24, it is to be understood that, for the purposes of this invention, the porous material can be incorporated into the material of the stent.

Detailed Description Text (13):
Coating with polymer may proceed immediately following application of the particulate material. A polymer is provided in a dilute solution and is applied to the particle-coated stent and mandrel. For example, polyurethane can be dissolved in NMP to make a 10% solution. Gel particles and particulate impurities can be removed from the solution by use of a clinical centrifuge. The polymer solution can be applied by dipping the mandrel into the solution and letting the solvent evaporate. With the solution of polyurethane and NMP, a single dip in the solution can provide a film of adequate thickness. To assist in the formation of communicating passageways through the polymer between the blood-contacting surface and the lumen-contacting surface, additional sodium bicarbonate particles are preferably dusted onto the polymer solution immediately after the dipping operation and before the polymer solution has

dried. Excess particulate material can be removed by gently tapping the mandrel. To precipitate and consolidate the polyurethane film on the stent, it can be dipped briefly (about 5 minutes) in water and then rolled gently against a wetted surface, such as a wet paper towel. The stent assembly can then be placed into one or more water baths over an extended period (e.g., 8 hours) to dissolve and remove the sodium bicarbonate. After drying in air at temperatures from about 20.degree. C. to about 50.degree. C., the film then can be trimmed to match the contour of the wire.

Detailed Description Text (43):
Wiktor type stents were placed over 3.0 mm diameter smooth glass rods and rolled by hand to assure a snug fit. The stent and rod assemblies were dipped in 1-methy-2-pyrrolidinone (NMP) alone at room temperature, allowed to drain vertically for a few seconds, then rotated horizontally while dusting with 400-500 mesh sodium bicarbonate until no further bicarbonate would adhere. After gently tapping the rod assemblies to dislodge lightly adherent bicarbonate, the assemblies were dipped once in a solution of 10 wt % polyurethane in NMP. After draining vertically for a few seconds, the rod and stent assemblies were rotated horizontally while dusting with 400-500 mesh sodium bicarbonate until no further sodium bicarbonate adhered, then gently tapped to dislodge lightly adherent sodium bicarbonate. The assemblies were immersed in water for about 5 minutes, then removed and the coating lightly compacted by gently rolling the coated stent on the mandrel against a wet paper towel. After immersing the stent assemblies in fresh water for at least 8 hours at room temperature the coated stents were removed from their mandrels and immersed in fresh water for 4-8 hours at room temperature. The coated stents were subsequently dried in a forced air oven at 50.degree. C. for about 8 hours and then trimmed of excess coating beyond the stent wires. After passing a visual inspection the porous polyurethane stents were ready for subsequent fibrin impregnation.

Other Reference Publication (5):
"Photolink Surface Modifications Technical Bulletin: Heparin Coatings for Medical Devices", Brochure from BSI Surface Modification Sciences, (1994).